Expert Report of Robert L. Buskey

The City of Huntington and Cabell County Commission v. AmerisourceBergen Drug Corporation, et al.

August 27, 2020

HIGHLY CONFIDENTIAL

G. The West Virginia Board of Pharmacy Determined ABDC Was In Compliance With the West Virginia CSA.

235. ABDC's Lockbourne, Ohio and Glen Allen, Virginia distribution centers—the main distribution centers that distribute controlled substances to West Virginia—have been continually licensed by the WV BOP, and both remain licensed today.[256] WV BOP has never once revoked or suspended either license and both remain active through June 20, 2021 (the next date for renewal). By granting and renewing ABDC's licenses, the WV BOP determined the issuance and renewal of these licenses was consistent with the public interest, [257] including that ABDC maintained effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and that ABDC complied "with applicable state and local law."[258]

VII. PLAINTIFFS' RELIANCE ON THE SIX METHODS IDENTIFIED BY CRAIG MCCANN AND SUPPORTED BY JAMES RAFALSKI IS UNREASONABLE.

236. I have reviewed the expert reports of plaintiffs' experts, Craig McCann and James Rafalski, and have focused my review on the methodologies and assumptions underlying their analysis of flagged orders.

237. The computer-based systems used by AmerisourceBergen to flag orders of interest are similar in design, and are better than, the methodologies set forth by Craig McCann and James Rafalski.

238. In addition, and as set forth below, the expert analysis of Craig McCann and James Rafalski is flawed because it relies on a faulty and unsupported assumption that AmerisourceBergen did not perform proper due diligence on its customers. The result of this faulty and unsupported assumption is that an inordinate amount of AmerisourceBergen orders are flagged.

A. No Distributor Is Required To Use Any Of The Six Methods Identified To "Flag" Orders.

239. To my knowledge, none of the methods identified by plaintiffs have been formally (or informally) endorsed by statute, the DEA, the WV BOP, or any other regulatory body as an acceptable or required methodology to identify suspicious orders. Even though Rafalski discusses six methods, and McCann applies data to six methods, Rafalski only claims that two of the six methods "provide[] a reasonable estimate and an initial trigger and first step to identifying orders of an unusual size."[259] Therefore, plaintiffs' own expert does not agree with all six of the methods that he offers.

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[256] *See* Dep. of Michael Goff, August 24, 2020, at 116:22-117:12 (testifying that ABDC distribution centers have been continuously licensed by the WV BOP since 1996).
[257] W.Va. Code. § 60A-3-303(a).
[258] *Id.*; *see also id.* § 60A-8-7 (setting forth licensing requirements for wholesale drug distributors); *see also* Dep. of Michael Goff, August 24, 2020, at 107:22-109:5; 116:22-117:12.
[259] Rafalski Report at 50.

240. Methods A and B—the two methods that Rafalski backs—are based on a case from 2017—just three years ago—involving a specific distributor's OMP. Applying these methods retroactively to every distributor's program from 1996 to 2017 is unsupported by any law, regulation, formal or informal guidance, or common sense.

241. Furthermore, even if these methods are applied retroactively, there has never been—and there is still not today—a requirement for distributors to use a specific methodology in their OMPs. Distributors have always had discretion to determine the methods used to flag orders and then ultimately determine which orders are suspicious.[260] So even if a distributor can use one of the methods identified by plaintiffs' experts, distributors can also use other methods not identified by plaintiffs that adequately flag and adjudicate orders.

B. McCann And Rafalski's Methods Produce Unreasonable And Inaccurate Results.

242. McCann provides no basis for his assumption that if a "flagged" order were not investigated, then all subsequent orders for the same drug must automatically be flagged. Such an assumption is inconsistent with the definition of a suspicious order. If an order is not of an unusual size, unusual frequency, or deviating substantially from a normal pattern (or is not otherwise suspicious), then it does not fall under the regulatory definition of a suspicious order. Following an initially-flagged order, McCann's assumption necessarily flags orders *only* because another order was flagged (which is not in and of itself suspicious)—not because the later order itself fits the definition of a suspicious order.

C. The Methods Identified By McCann And Rafalski Are Arbitrary.

243. Application of these methods is arbitrary. The DEA recognized that application of arbitrary methods is inappropriate: "DEA and our state partners have repeatedly and emphatically informed distributors that arbitrary thresholds are inappropriate, negatively impact legitimate patients, are an inadequate substitute for fulfilling their obligations under the CSA."[261]

244. The DEA has also recently stated that using "fixed thresholds to identify suspicious orders . . . [is] not helpful or useful because the information is often not

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[260] Dep. of Demetra Ashley, March 15, 2019, at 88:2-18 ("Q. To your knowledge, is there a particular formula or algorithm that is required for a legally compliant system? . . . A. To my knowledge, there is not. Q. To your knowledge, does a legally compliant system need to be automated? A. No, it does not. Q. Does it need to be manual, i.e., the opposite of automated? . . . THE WITNESS: It's not specific. There's no direction on how to do it."); *id.* at 89:5-12 ("Q. And the criteria that determines whether it deviates from pattern or too large or anything else is criteria that is to be set by the distributors? A. Correct. Q. And so it's within their discretion; is that correct? A. That's correct."); Dep. of Michael Mapes, July 11, 2019, at 85:5-11 ("In your experience, DEA affords registrants the discretion to design a suspicious order monitoring system that is effective? . . . THE WITNESS: Yes."); Dep. of Thomas Prevoznik, April 17, 2019, at 179:22-180:11 ("Q. Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A. Yes. Q. And there's no single feature that makes a suspicious order monitoring system compliant, correct? A. Correct. Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct.").

[261] Pharmaceutical Commerce, *GAO advises DEA to be more forthcoming with guidance on suspicious order monitoring of controlled substances*, https://pharmaceuticalcommerce.com/latest-news/gao-advises-dea-to-be-more-forthcoming-with-guidance-on-suspicious-order-monitoring-of-controlled-substances/ (July 28, 2015).

actionable."[262] This statement is consistent with the two goals of the DEA: prevent diversion and ensure patients who have legitimate prescriptions have access to their medication.[263] For example, reporting 90.6% of all oxycodone and 91.1% of all hydrocodone orders placed, as Rafalski claims ABDC should have under Method A in Cabell County and the City of Huntington, would be inconsistent with that goal.[264]

245. The DEA has recognized that most diversion of prescription opioid medication occurs outside of the closed system of distribution (*i.e.*, taken from medicine cabinets or sold or given to friends or relatives).[265] The DEA has never expected an OMP to identify and prevent that type of diversion. Instead, the expectation is to detect orders that may contribute to diversion that occurs within the closed system of distribution.

246. The DEA has estimated that diversion occurring within the closed system of distribution is infrequent: The DEA sets quotas—the maximum amount of a particular opioid that is allowed to be manufactured. Within these quotas, the DEA now estimates the amount it believes was diverted in a certain year in order to set the following year's quota. Recently, the DEA estimated that only 0.056% of hydrocodone and only 0.072% of oxycodone was diverted in 2018.[266]

247. Plaintiffs' proposed methods are irreconcilable with distributors' obligations under the West Virginia CSA and the federal CSA and the regulatory definition of a suspicious order. The definition of a suspicious order requires distributors to review "unusual" orders. By

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[262] *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, Gov. Accountability Office, GAO-20-118, at 32 (January 2020).

[263] Dep. of Demetra Ashley, March 15, 2019, at 197:22-25 ("Part of the mission of the Office of Diversion Control is to ensure an adequate supply of controlled substances are available to meet legitimate medical need."); *see also* Dep. of Joe Rannazzisi, May 15, 2019, at 500:1-14 ("[I]f we have a quota and we decide to cut the quota by 20 percent, you still have the same amount of people kind of drawing from that quota. Well, if it's 20 percent less, patients might not get their medication. If it's a drug seeker, you know, no one really cares, but if it's a -- if it's a person who actually needs that opioid, a hospice care patient, a palliative care patient, somebody that indeed needs opioids for transition or whatever, you know, their final stages of life. If they can't get that medication, they are in pain, then we haven't met our obligations under 826.").

[264] *See* Rafalski Report at 48.

[265] U.S. Dep't of Justice, DEA 2018 National Drug Threat Assessment at Figure 10; *see also* Statement of J. Rannazzisi to U.S. Senate Hearing on "America's Addiction to Opioids: Heroin and Prescription Drugs," May 14, 2014 at 3 ("These increasing costs make it difficult, especially for teens and young adults, to purchase in order to support their addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends.").

[266] The SUPPORT Act, signed into law in October 2018, now requires the DEA to calculate rates of diversion when setting production quotas for the following year. *See* DEA, *Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020* (Sept. 12, 2019), *available at* https://www.deadiversion.usdoj.gov/fed_regs/quotas/2019/fr0912.htm. When calculating the quotas for 2020, the DEA estimated rates of diversion in 2018 for five drugs. *Id.* DEA estimated that 57.051 kg of oxycodone and 24.259 kg of hydrocodone were diverted in 2018. *Id.* In 2018, the quotas for oxycodone and hydrocodone were 79,596.606 kg and 43,027.640 kg respectively. DEA Production Quota History. Thus, in comparing the 2018 quotas with DEA's estimates of diversion in 2018, DEA's estimates reflect that 0.056% of hydrocodone was diverted in 2018 and 0.072% of oxycodone was diverted in 2018. Although I am not familiar with the methodology DEA used to reach these conclusions, and I cannot speak to the accuracy, it is notable that DEA itself has concluded that an extremely small amount of oxycodone and hydrocodone are being diverted within the closed system of distribution.